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10/561,985	01/13/2006	Philip Alfred Ropp	2003.795US	1515
67706 7590 09/23/2008 ORGANON USA, INC. c/o Schering-Plough Corporation 2000 Galloping Hill Road Mail Stop: K-6-1, 1990 Kenilworth, NJ 07033				
EXAMINER DEVI SARVAMANGALA 7N				
ART UNIT		PAPER NUMBER		
1645				
NOTIFICATION DATE		DELIVERY MODE		
09/23/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

## Application No.

10/561,985

## Applicant(s)

ROPP ET AL.

## Examiner

S. Devi, Ph.D.

## Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 122105 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date 011706
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Preliminary Amendment**

- 1) Acknowledgment is made of preliminary amendment filed 12/21/05.

### **Election**

- 2) Acknowledgment is made of election filed 06/13/08 in response to the species election requirement mailed 03/13/08. Applicants have elected, the 1,2-hexanediol species; heat shock protein species; and the *E. coli* bacterial expression system species. Applicants identify the claims readable on the elected species. Because Applicants did not distinctly and specifically point out the supposed errors in the species election requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

### **Status of Claims**

- 3) Claims 1-18 are pending and are under examination. A First Action on the Merits is issued herein on these claims. Since both 1,2-hexanediol and 1,6-hexanediol species were speciated under the same group, both of these species have been examined.

### **Information Disclosure Statement**

- 4) Acknowledgment is made of Applicants' Information Disclosure Statement filed 01/17/06. The information referred to therein has been considered and a signed copy is attached to this Office Action.

### **Priority**

- 5) The instant application is a national stage 371 application of the PCT application PCT/US04/18992, filed 06/15/2004, which claims priority to the provisional applications 60480899 and 60488596 filed 06/24/2003 and 07/18/2003 respectively.

### **Objection to Specification**

- 6) The specification of the instant application is objected to for the following reason:  
The use of the trademarks in the instant specification has been noted in this application. For example, see pages 5, 11, 15, 20, 21, 23 and 26 for 'Zwittergent'; see pages 5 and 11 for 'Zw 3-14'; see pages 11 and 15-25, for 'Sephacrose'; and see page 13 for 'Pyrotell-T'. The trademark

recitations should be capitalized wherever they appear. See M.P.E.P 608.01(V) and Appendix I. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification and make necessary changes wherever trademark recitations appear.

### **Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

**7) The following is a quotation of the second paragraph of 35 U.S.C. § 112:**

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

**8) Claims 1-18 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.**

(a) Claims 1 and 17 are indefinite in the limitations: ‘a portion of the LPS’ and ‘a portion of the protein’, because it is unclear what is encompassed in the limitation ‘a portion’. What constitutes ‘a portion’, and how much of the LPS’s and the protein’s original structure has to be retained such that the resulting LPS or protein can be considered ‘a portion’, is not clear. The metes and bounds of the structure encompassed in the limitation ‘a portion’ of the LPS and ‘a portion’ of the protein is indeterminate. Does half of the lipid A component of the LPS qualify as ‘a portion of the LPS’?

(b) Claim 14 is indefinite in the limitation: ‘a portion of the endotoxin’ (see line 3), because it is unclear what is encompassed in the limitation ‘a portion’. What constitutes ‘a portion’, and how much of the endotoxin’s original structure has to be retained such that the resulting endotoxin can be considered ‘a portion’, is not clear. The metes and bounds of the structure encompassed in the limitation ‘a portion’ of the endotoxin is indeterminate.

(c) Claim 1 is indefinite in the limitations: ‘an endotoxin’ and ‘a Lipopolysaccharide (LPS)’, because it is unclear how one differs from the other in terms of scope.

(d) Claim 1 has improper antecedent basis in the limitation: ‘the LPS’ (see line 4), because while there is an earlier recitation of ‘a Lipopolysaccharide (LPS)-protein complex’ in the claim, there is no earlier recitation of a LPS.

(e) Claim 1 has improper antecedent basis in the limitation: 'the protein' (see last line), because while there is an earlier recitation of 'a Lipopolysaccharide (LPS)-protein complex' and of 'recombinantly produced proteins' in the claim, there is no earlier recitation of a protein.

(f) Analogous rejection and criticism apply to claim 17 with regard to the limitation: 'the protein' (see lines 4 and 8).

(g) Claim 7 is indefinite and confusing in the limitation: 'LPS or other endotoxin'. It is unclear what is encompassed in the limitation: 'other endotoxin'. How LPS differs from 'other endotoxin' in terms of scope is not clear. Is this 'other endotoxin' different from 'an endotoxin' recited in the base claim 1?

(h) Claim 7 is indefinite and confusing in the limitation: 'LPS'. Claim 7 depends from claim 1, which includes the limitation 'the LPS' in line 4. Is the 'LPS' recited in claim 7 different from the one recited in claim 1?

(i) Claim 11 is indefinite in the limitation: 'high salt environment'. The term 'high' is a relative term which is not specifically defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree, and therefore one of ordinary skill in the art would not be reasonably apprised of the scope of the term in the claim. What precise environment qualifies as 'a high salt environment' is unclear.

(j) Claim 13 is vague and indefinite in the limitation: 'changing the pH', because it is unclear the pH of what is being changed, and from what pH to what other pH.

(k) Analogous rejection and criticism apply to claim 8 with regard to the limitation: 'a change in pH or conductivity' and to claim 17 with regard to the limitation: 'changing the pH or the conductivity'.

(l) Claims 2-13, 15, 16 and 18, which depend directly or indirectly from claims 1, 14 or 17, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

### **Rejection(s) under 35 U.S.C. § 102**

9) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in–

(2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

**10)** Claims 1-3, 5, 6, 8-10, 11, 14, 15, 17 and 18 are rejected under 35 U.S.C. § 102(e)(2) as being anticipated by Hauser *et al.* (US 6,966,992) in light of Petsch *et al.* (*J. Biotechnol.* 76: 97-119, 2000 – Applicants' IDS).

Hauser *et al.* disclosed a method of purifying proteins produced by recombinant DNA techniques from its impurities including carbohydrates and lipids using a chromatographic resin and a buffer containing non-inflammable, cheaper and less denaturing solvent, 1,6-hexanediol, 1,5-pentanediol, or 1,7 heptanediol. The method purifies a recombinant polypeptide from a mixture after the mixture is applied to a chromatographic column and the molecule is eluted from the column with a buffer containing 1,6-hexanediol, 1,5-pentanediol, or 1,7 heptanediol. The polypeptide molecule is produced via recombinant *E. coli*. The buffer has a pH of about 2.0 to 12.0; and the pH is changed to about 2 to 6 in acidic (anionic) chromatography and to about 8 to 12 in basic (cationic) chromatography. The resin is in 200 mM NaCl solution, i.e., high salt environment. The proteins that can be purified by Hauser's method are not limited to those mentioned in the paragraph bridging columns 6 and 7. See abstract; claims; 'Summary of the Invention' in column 2; first paragraph under section 5.2 in column 6; first full paragraph in column 6; lines 34-36 in column 4; columns 5 and 8; and first full paragraph in column 6. That the prior art method inherently serves as a process of removing an endotoxin from the mixture of polypeptides from the endotoxin-containing recombinant Gram negative *E. coli* cells is inherent from the disclosure of Hauser *et al.* in light of what is known in the art. For instance, Petsch *et al.* taught endotoxin to be a common impurity in recombinant protein solutions from recombinant *E. coli* that is removed via chromatography, and showed that endotoxin intrinsically comprises both lipid and carbohydrate moieties. See abstract; Figure 1; and section 3. Since the prior art process meets the instantly claimed method, it is expected to necessarily bring about the same effects and serve as a process of removing an endotoxin from a mixture of polypeptides recombinantly produced via the endotoxin-containing recombinant *E. coli* cells.

Claims 1-3, 5, 6, 8-10, 11, 13-15, 17 and 18 are anticipated by Hauser *et al.* Petsch *et al.* is **not** used as a secondary reference in combination with Hauser *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Hauser *et al.* with the unrecited limitation(s) being inherent in view of what is known in the art as explained above. See *In re Samour* 197 USPQ 1 (CCPA 1978).

### **Claim(s) Objections**

- 11)** Claim 1 is objected to for the incorrect limitation: ‘an’ chromatographic resin.

### **Remarks**

- 12)** Claims 1-18 stand rejected.

**13)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

**14)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

**15)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Shanon Foley, can be reached at (571) 272-0898, or Robert Mondesi, can be reached at (571) 272-0956.

/S. Devi/  
S. Devi, Ph.D.  
Primary Examiner  
AU 1645

September, 2008